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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,868	03/10/2004	James L. Hartley	0942.285000K/BJD/JKM	2652
26111	7590	01/25/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005				VOGEL, NANCY S
ART UNIT		PAPER NUMBER		
		1636		

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/796,868	HARTLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 2-39 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 2-18 and 21-37 is/are rejected.  
 7) Claim(s) 19,20,38 and 39 is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_.

## DETAILED ACTION

Claims 2-39 are pending in the case.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2-6, 8-13, 15-18, 21-25, 27-32, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffiths et al. (US Patent 6,010,884).

Griffiths et al. disclose compositions comprising at least two isolated recombination proteins, at least one first nucleic acid molecule comprising a first recombination site and a second recombination site wherein said first and second recombination sites do not recombine with each other, and at least one second nucleic acid molecule comprising a first recombination site and a second recombination site

wherein said first and second recombination sites do not recombine with each other (see column 1, lines 35-37, and column 5, lines 36-67). Since the reference discloses at column 1, lines 35-37, that the disclosed method of recombination can be performed in vitro using soluble recombinase, the reference discloses the composition or kit comprising the above listed elements in vitro, ie outside a cell. The reference discloses that the first and second molecule may be circular or linear nucleic acid molecules such as plasmids, phages or phagemid (see column 5-9). The reference discloses the composition wherein any recombinase may be used, including Cre, which is encoded by the bacteriophage P1 phage (see column 7, lines 5-11), the IHF, Int, and Xis system which is encoded by the bacteriophage lambda (see column 6, lines 44-column 7, line 4), or Flp (see column 7, lines 9-11). Note that the recitation of "at least two [or three] isolated recombination proteins" encompasses the embodiment in which the two recombination proteins are the same, but two or more molecules are present.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-6, 8-18, 21-25, 27-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (US Patent 6,010,884) in view of Baum et al. (J. Bacteriol., 176 (10):2835-2845, 1994).

Griffiths et al is cited for the reasons set forth in the above rejection.

The difference between the reference and the claims is that in the claims, at least one of the recombination proteins is encoded by *B. thuringiensis*.

However, Baum et al. disclose recombination proteins encoded by *B. thuringiensis* and their function as site specific recombinases (see abstract and page 2835, first and second column).

It would have been obvious to one of ordinary skill to have utilized known recombination proteins encoded by *B. thuringiensis*, as disclosed by Baum et al., in the compositions disclosed by Griffiths et al., since both references disclose methods of manipulating DNA structure using site specific recombination proteins. One would have been motivated to use *B. thuringiensis* recombination proteins since Griffiths et al. disclose that any recombination protein may be used, and since Baum et al. disclose such proteins from a known and useful bacterial species, *B. thuringiensis*. Based upon

the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 2-13, 15-18, 21-32 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (US Patent 6,010,884) in view of Savakis et al. (US Patent 6,225,121).

Griffiths et al. is cited for the reasons set forth above.

The difference between the reference and the instant claims is that the second nucleic acid molecule comprises at least one toxic gene and at least one selectable marker on different nucleic acid segments, separated by at least one recombination site.

However, Savakis et al. disclose vectors comprising a toxic gene and a selectable marker gene, separated by a recombination site, and the usefulness of these components in selection procedures in genetic recombination systems (see columns 7, 8, 10 and 17-20).

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Griffiths et al. and Savakis et al., since both references are concerned with compositions for genetic recombination, including selecting for recombination events. One would have been motivated to have done so by the desire to select for recombination events, using known selection systems comprising selectable markers and toxic genes, as disclosed by the references. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the

contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 14 of U.S. Patent No. 6,720,140. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2 and 21 are generic to all that is recited in claims 5 and 14 of US Patent No. 6,720,140. That is, claims 2 and 21 of '140 fall entirely within the scope of claims 2 and 21, or in other words, claims 2 and 21 are anticipated by claims 5 and 14 of '140. Specifically, the claims of the '140 disclose the same composition or kit as that recited in the instant application, i.e. comprising at least two isolated recombination proteins, at least one first nucleic acid molecule ("Insert Donor DNA molecule") comprising a first recombination site and a second

recombination site wherein said first and second recombination sites do not recombine with each other, and at least one second nucleic acid molecule ("Vector Donor DNA molecule") comprising a first recombination site and a second recombination site wherein said first and second recombination sites does not recombine with each other. While claims 5 and 14 of '140 recite that the second nucleic acid comprises a repression cassette encoding a repressor and a selectable marker that is repressed by the repressor, the claims of the instant application are generic to this embodiment and therefore, the instant claims are anticipated by the claims 5 and 14 in the conflicting patent '140.

Claims 19, 20, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Nancy Vogel*  
Nancy Vogel  
Patent Examiner